



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

**Solicitation of Information and Recommendations for
Revising OIG's Non-Binding Criteria for Implementing
Permissive Exclusion Authority Under Section 1128(b)(7) of
the Social Security Act**

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice and Opportunity for Comment.

SUMMARY: This *Federal Register* notice informs the public that OIG: (1) is considering revising the Non-Binding Criteria for Implementing Permissive Exclusion Authority Under Section 1128(b)(7) of the Social Security Act (62 FR 67392, December 24, 1997), and (2) is soliciting input from the public for OIG to consider in developing the revised criteria.

DATES: To ensure consideration, public comments must be delivered to the address provided below by no later than 5 p.m. on [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: In commenting, please refer to file code OIG-1271-N. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific recommendations and proposals through the Federal eRulemaking Portal at <http://www.regulations.gov>.

2. *By regular, express, or overnight mail.* You may send written comments to the following address: Patrice Drew, Office of Inspector General, Department of Health and Human Services, Attention: OIG-1271-N, Room 5296, Cohen Building, 330 Independence Avenue, SW, Washington, DC 20201. Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver, by hand or courier, your written comments before the close of the comment period to Patrice Drew, Office of Inspector General, Department of Health and Human Services, Cohen Building, 330 Independence Avenue, SW, Washington, DC 20201. Because access to the interior of the Cohen Building is not readily available to persons without Federal Government identification, commenters are encouraged to schedule their delivery with one of our staff members at (202) 619-1368.

For information on viewing public comments, please see the Supplementary Information section.

FOR FURTHER INFORMATION CONTACT: Patrice Drew, Department of Health and Human Services, Office of Inspector General, Office of External Affairs, at (202) 619-1368.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the end of the comment period are available for viewing by the public. All comments will be posted on <http://www.regulations.gov> as soon as possible after the closing of the comment period. Comments received timely will also be available for public inspection as they are received at Office of Inspector General, Department of Health and Human Services, Cohen Building, 330 Independence Avenue, SW, Washington, DC 20201, Monday through Friday of each week from 10 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (202) 619-1368.

BACKGROUND:

Section 1128(b)(7) of the Social Security Act (Act) authorizes the Secretary, and by delegation the Inspector General, to exclude an individual or entity from

participation in the Federal health care programs for engaging in conduct described in sections 1128A and 1128B of the Act. In general, OIG may seek to exclude any person who violates the Federal False Claims Act, 31 U.S.C. 3729-3733, or the Civil Monetary Penalties Law, section 1128A of the Act. For example, submitting or causing the submission of false or fraudulent claims or soliciting or paying kickbacks in violation of the Federal Anti-Kickback Statute, section 1128B of the Act, can result in exclusion from participation in Medicare, Medicaid, and all other Federal health care programs. On October 24, 1997, OIG published a proposed policy statement in the *Federal Register* (62 FR 55410) in the form of non-binding criteria to be used by OIG in assessing whether to impose a permissive exclusion under section 1128(b)(7) of the Act. On December 24, 1997, OIG published the final policy statement in the *Federal Register* (62 FR 67392).

Since 1997, OIG has used these criteria to evaluate whether to impose a permissive exclusion under section 1128(b)(7) of the Act or release this authority in exchange for the defendant's entering into an Integrity Agreement with OIG. On the basis of our experience evaluating permissive exclusion in False Claims Act and administrative cases over

the past 17 years, we are considering revising the existing criteria. We believe revised criteria may help the provider community understand how OIG exercises its discretion in cases under section 1128(b)(7) of the Act. We also believe that updated guidance could better reflect the state of the health care industry today, including the changes in legal requirements and the emergence of the health care compliance industry.

In considering possible revisions to the criteria, we are soliciting comments, recommendations, and other suggestions from concerned parties on how best to revise the criteria to address relevant issues and to provide useful guidance to the health care industry. The issues we are considering include, but are not limited to: (1) whether there should be differences in the criteria for individuals and entities and (2) whether and how to consider a defendant's existing compliance program.

After reviewing any timely submitted comments, we will decide whether and how to revise the non-binding criteria for use in evaluating exclusion under 1128(b)(7) of the Act where the defendant has defrauded the Federal health care programs.

Dated: June 7, 2014.

Daniel R. Levinson,
Inspector General.

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